

REMARKS

The courtesies extended to Applicant's representative by Examiners Ernst V. Arnold and Alton Pryor at the interview held October 17, 2006, are appreciated. As discussed at the interview, an affidavit by the Applicant is attached hereto. Additional reasons presented at the interview as warranting favorable action are incorporated into the remarks below and constitute Applicant's record of the interview.

Favorable reconsideration of this application is respectfully requested in view of the claim amendments and following remarks. Claims 23-25 have been added. Claims 1-4, 6, 7, 10-12, 14, and 19-21 have been amended. Claims 8 and 18 have been cancelled. Currently, claims 1-7, 9-17, and 19-25 are pending in the present application of which claims 1, 12, 19, 21, and 23 are independent. As required by the Examiner, an amended abstract is provided. No new matter has been added.

Claims 1-17 and 19-22 were rejected under 35 U.S.C. §112, first paragraph, because the specification allegedly does not provide enablement for treating patients with all disorders marked by a loss of pigmentation. Claims 1-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,985, 443 to Montes, in view of "Vitiligo and Other Hypomelanoses of Hair and Skin", 1983 to Ortonne et al. (hereinafter "Ortonne"), "International Journal of Artificial Organs 2000", 23(8), 568, to Kolyadenko et al. (hereinafter "Kolyadenko") and "Alternative Medicine Review" 1997, 2(2), pages 116-127, to Kelly. The above rejections are respectfully traversed for at least the reasons set forth below.

Claim Rejection Under 35 U.S.C. §112

Claims 1-17 and 19-22 were rejected under 35 U.S.C. §112, first paragraph, because the specification, while enabling for treatment of vitiligo or grey hair, allegedly does not provide enablement for treating patients with all disorders marked by a loss of pigmentation. Claim 1 has accordingly been amended to replace the language “disorders marked by a loss of pigmentation” with the language “vitiligo or grey hair.” Independent claims 12, 19, and 21 have also been amended to replace the language “treating disorders marked by a loss of pigmentation” with the language “restoring pigmentation of skin or hair,” after consultation with the Examiners at the Examiner’s Interview. The specification clearly provides support and enablement for restoring pigmentation of skin or hair in Paragraph [0001]. The Examiner is therefore respectfully requested to withdraw the rejection of claims 1, 12, 19, and 21, as well as their dependent claims 2-7, 9-11, 13-17, 20, and 22.

Claim 20 was rejected under 35 U.S.C. §112, second paragraph as having insufficient antecedent basis for the limitation “said female patient” in the claim. Claim 20 has accordingly been amended to depend from Claim 19, which contains the correct antecedent basis “a female patient,” as noted by the examiner.

Claim Rejection Under 35 U.S.C. §103

The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in MPEP § 706.02(j):

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Therefore, if the above-identified criteria are not met, then the cited reference(s) fails to render obvious the claimed invention and, thus, the claimed invention is distinguishable over the cited reference(s).

Claims 1-22 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,985,443 to Montes, in view of “Vitiligo and Other Hypomelanoses of Hair and Skin”, 1983 to Ortonne et al. (hereinafter “Ortonne”), “International Journal of Artificial Organs 2000”, 23(8), 568, to Kolyadenko et al. (hereinafter “Kolyadenko”) and “Alternative Medicine Review” 1997, 2(2), pages 116-127, to Kelly. This rejection is respectfully traversed because Montes, Ortonne, Kolyadenko and Kelly, considered singly or in combination, fail to teach or suggest the claimed invention as set forth in claims 1, 12, 19, 21, and their dependents.

Montes discloses treatment of vitiligo with intramuscular vitamin B12; oral folic acid; and oral vitamin C.

Ortonne and Kolyadenko each disclose treatment of vitiligo or skin depigmentation with copper. Ortonne also teaches use of pantothenic acid.

Kelly shows treatment of vitiligo with oral HCl salts administered at mealtimes; a connection between gastric acidity and skin diseases is drawn.

Claims 1, 12, and 21 each recite administering an effective amount of vitamin B12, copper, folic acid, and vitamin C to a patient suffering from vitiligo or grey hair. Amended claims 1 and 21 each specify that the vitamin B12 is orally administered in a composition further comprising at least copper. Amended claim 12 specifies that the vitamin B12, copper, folic acid, and vitamin C are compounded as a topical formulation. Amended claim 21 recites administration of a composition comprising an effective daily amount of vitamin B12, an effective daily amount of copper, an effective daily amount of folic acid, and an effective daily amount of vitamin C, in conjunction with a step of exposing depigmented skin or hair of the patient to the sun or to ultraviolet light. The Official Action appears to admit that Montes does not teach all the elements of the independent claims; specifically, copper, along with other ingredients recited in the dependent claims, is not taught by Montes for treating vitiligo.

The Official Action states that “it would have been obvious to one of ordinary skill in the art... to add administering an effective amount of: copper... to a patient suffering from a loss of pigmentation, as suggested by the combined teachings of Ortonne et al., Kolyadenko et al., and Kelly, in the method of Montes...” The Official Action alleges that one of ordinary skill in the art would have been motivated to do this, not because of any teachings within the cited art, but rather because “the idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, 1072 (CCPA 1980).

The applicant, through his representative, respectfully disagrees with this position.

Montes discloses intramuscular vitamin B12, whereas amended claims 1 and 21 of the current application is directed to oral administration of vitamin B12 in a composition additionally comprising at least copper. Similarly, amended claim 12 is directed to a topical composition for treatment of vitiligo which comprises vitamin B12, copper, folic acid, and vitamin C, rather than administration of oral vitamin C and folic acid in conjunction with intramuscular vitamin B12, as recited in Montes. Montes fails to teach or suggest oral or topical administration of vitamin B12. Additionally, Montes teaches away from administration of a composition comprising vitamin B12, copper, folic acid, and vitamin C, as recited in Claim 12, since vitamin B12 is clearly administered in an intramuscular composition, while folic acid and vitamin C are clearly administered in a different oral composition or compositions. Similarly, Montes teaches away from oral administration of vitamin B12, as recited in claim 1, since Montes teaches that vitamin B12 should be administered intramuscularly, even when other active ingredients are being orally administered.

Ortonne and Kolyadenko each teach administration of copper to treat vitiligo. However, Ortonne and Kolyadenko each fail to teach oral or topical administration of vitamin B12, as required in claims 1 and 12. Kelly teaches administration of dietary HCl to treat vitiligo. However, Kelly fails to teach oral or topical administration of vitamin B12, as required in claims 1 and 12.

At least by virtue of Montes's, Ortonne's, Kolyadenko's, and Kelly's failure to teach or suggest oral or topical administration of vitamin B12 in combination with administration of

copper, folic acid, and vitamin C, a *prima facie* case of obviousness has not been established under 35 U.S.C. § 103. Accordingly, the Examiner is respectfully requested to withdraw the rejection of claims 1 and 12. Claims 2-5, 9, and 16-18 depend from allowable claim 1; and claims 13-15 depend from allowable claim 12; these dependent claims are also allowable over Montes in view of Ortonne, Kolyadenko and Kelly at least by virtue of their dependencies.

Amended claim 19 describes treatment with copper while a female patient is not undergoing menses, but not while a female patient is undergoing menses. With regard to claim 19, the examiner asserts that “the method of treating disorders marked by a loss of pigmentation is obvious whether administered to a female undergoing menses or not undergoing menses.” However, amended claim 19 specifies treatment with a composition comprising an effective daily amount of vitamin B12, an effective daily amount of copper, an effective daily amount of folic acid, and an effective daily amount of vitamin C while a female patient is not undergoing menses. While a female patient is undergoing menses, amended claim 19 specifies treatment with an effective daily amount of vitamin B12, an effective daily amount of folic acid, and an effective daily amount of vitamin C in the absence of copper supplementation. However, the examiner has failed to provide any teaching that would lead one of ordinary skill in the art to administer copper to a female patient with disorders requiring repigmentation therapy during one part of her menstrual cycle, but not during another part of her menstrual cycle. Ortonne and Kolyadenko each teach administration of copper to treat vitiligo. However, Ortonne and Kolyadenko each fail to teach administration of different amounts of copper during different phases of a woman’s menstrual cycle, or cessation of copper supplementation during part of a

woman's menstrual cycle, as required in claim 19. Montes and Kelly each fail to make up for this deficiency in Ortonne and Kolyadenko, since they fail to specify use of copper to treat vitiligo at all, much less in a manner which depends on a woman's menstrual cycle. Therefore, a *prima facie* case of obviousness has not been established under 35 U.S.C. § 103. Accordingly, the Examiner is respectfully requested to withdraw the rejection of claim 19. Claim 20 depends from allowable claim 19; this dependent claims is also allowable over Montes in view of Ortonne, Kolyadenko and Kelly at least by virtue of its dependency.

Newly Added Claims

Claims 23-26 have been added. Claim 23 includes a method of restoring pigmentation of skin or hair in a human patient in need thereof, by administering an effective amount of vitamin B12 to said patient; and by orally administering a composition comprising 0.7-3 mg copper, 0.15-50 mg folic acid and 15-1000 mg vitamin C to the patient. Ortonne and Kolyadenko each fail to teach the amount of orally administered copper that is effective in treatment of vitiligo. Kolyadenko only appears to teach topical administration of copper. Ortonne teaches that administration of copper to rats assists in repigmentation; however, in the absence of undue experimentation, a person of ordinary skill in the art would not be able to extrapolate the amount of copper which is effective in humans from the amount of copper which is effective in rats, particularly when other active ingredients (folic acid and vitamin C) which were not used to treat the rats are added to the composition used in treatment of humans. Amended claims 6, 7, 10, 11, and new claims 24-26 depend upon claim 23 and are allowable at least by virtue of their dependencies. Therefore, the Examiner is respectfully requested to allow claims 6, 7, 10, 11, and 24-26.

Objective Evidence of Patentability

Attached please find the Declaration Under 37 CFR 1.132 by Audrey VanStockum, the inventor of the invention described in the current application and President of Supernatural Health, Inc. Supernatural Health, Inc., markets Recouleur[®] nutritional supplement formulation, a composition which is covered by the claims of the current application. This nutritional supplement is specifically formulated to stimulate repigmentation in patients having vitiligo or gray hair. In her Declaration, Ms. VanStockum provides evidence of commercial success, showing that in 2004, Supernatural Health, Inc., sold 833 jars, each containing a six month supply. In 2005, Supernatural Health, Inc. sold 2,084 jars, and in the first nine months of 2006, the company sold 3,012 jars. Supernatural Health, Inc., anticipates making a net profit in 2006. More importantly, she notes that one third of the company's customers make repeat purchases. Her declaration also shows that the current invention fulfils a long-felt need in the art, in that, with the exception of Recouleur[®], there is, to her knowledge, no nutritional supplement currently on the market which effectively treats vitiligo.

The effectiveness of Recouleur[®] is demonstrated in the photographic evidence accompanying the attached affidavit. Patients L.J., J.S., and M.A. each experienced significant repigmentation of vitiliginous skin within three to six months after beginning to take Recouleur[®]. In the case of L.J., this is particularly noticeable, upon comparing Exhibit 1 (photographs taken prior to treatment) and Exhibit 2 (photographs taken after three months of treatment), in the increased pigmentation around his lips and chin and in the darker skin on his fingers and palms. J.S., upon comparing Exhibit 3 (photographs taken prior to treatment) and Exhibit 4 (photographs taken after six months of treatment), exhibits increased pigmentation under his lower lip and on the backs of his hands. M.A., upon comparing Exhibit 5 (photographs taken prior to treatment) and Exhibit 6 (photographs taken after six months of treatment), exhibits increased pigmentation in vitiliginous skin on her hands and arms. The long-felt need for Recouleur[®] is made even more clear when we note that the patients L.J. and M.A. had each been treated with Psoralen plus UVA light (a conventional vitiligo treatment), with little or no success. L.J. had also been taking corticosteroids (another conventional vitiligo treatment) prior to treatment with Recouleur[®], again with limited success.

Conclusion

In light of the foregoing, withdrawal of the rejections of record and allowance of this application are earnestly solicited.

While we believe that the instant amendment places the application in condition for allowance, should the Examiner have any further comments or suggestions, it is respectfully requested that the Examiner telephone the undersigned attorney in order to expeditiously resolve any outstanding issues.

In the event that the fees submitted prove to be insufficient in connection with the filing of this paper, please charge our Deposit Account Number 50-0578 and please credit any excess fees to such Deposit Account.

Respectfully submitted,
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